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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,586	12/15/2003	Richard Lewis Veech	604-703	1400

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NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
ZHANG, NANCY L	
ART UNIT	**PAPER NUMBER**
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,586	VEECH, RICHARD LEWIS	
	Examiner	Art Unit	
	Nancy L. Zhang	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group III, drawn to a method of producing a physiologically acceptable ketosis comprising oral administration of a cyclic oligomer of formula (I), in the reply filed on 9/25/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-7 and 11-18 are withdrawn from consideration because they are not directed to the elected invention.

Claims 8-10 are examined.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it includes two paragraphs and it uses the word "such as". Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 8, the omission of the structure of "formula (I)" renders the claim indefinite because it is unclear what formula (I) is part of the claimed invention. See MPEP § 2173.05(d). For examination purpose, formula (I) of claim 8 is interpreted as formula (I) in applicant's specification on page 4 where n is 1.

The recitation of "a physiologically acceptable ketosis" renders the claim indefinite because ketosis is "a stage in metabolism occurring when the liver converts fat into fatty acids and ketone bodies which can be used by the body for energy" (see the definition on http://en.wikipedia.org/wiki/Ketosis). It is unclear what the limitation is for "a physiologically acceptable ketosis". For examination purposes, claim 8 is interpreted as "a method of producing ketosis comprising oral administration of a cyclic oligomer of formula (I)".

Claim Rejections - 35 USC § 103

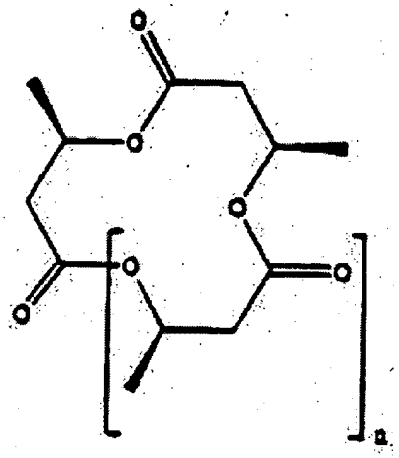
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin et al. (US Patent 6,380,244, filing date: Jul. 22, 1999).

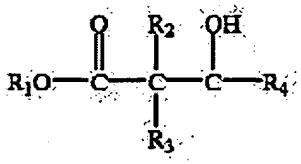
Claims 8-10 are directed to a method of producing a physiologically acceptable ketosis in a human or animal comprising oral administration of a cyclic oligomer of formula (I) which is a cyclic ester of (R)-3-hydroxybutyrate shown as follows:



Further limitations include: that the animal is fed with less than 50% by weight of its caloric content of its diet of fat (claim 9); and that the animal is fed with less than 25% by weight of its caloric content of its diet of fat (claim 10).

Martin et al. teach a method of modulating blood ketone levels in a mammal comprising administering to the mammal a nutritional or therapeutic dietary composition comprising a 3-hydroxyacid derivative such as linear oligomers of 3-hydroxyacids or cyclic oligomers of 3-hydroxyacids (column 11, lines 49-56).

The general formula for 3-hydroxyacids is:



Martin et al. also disclose that the composition can be administered orally (see abstract, line 21). Martin et al. further disclose an example of feeding rats with 3-hydroxybutyrate oligomer (column 11, Example 7) where the rats were switched to a control diet containing 75% of the calories from starch, 20% as casein and 5% as polyunsaturated oil, plus mineral mix and liver extract supplements (column 11, lines 6-9). This clearly indicates that the rats in Martin et al.'s disclosure were fed with a diet containing less than 25% by weight of its caloric contents as fat which meets the limitation of the instant claims 9 and 10.

The difference between Martin et al.'s disclosure and Martin et al.'s disclosure lies in that Martin et al. do not teach the administering of a cyclic oligomer having the structure of formula (I) of the instant application. However, cyclic oligomers of 3-hydroxyacids are derivatives of 3-hydroxyacid as disclosed by Martin et al. and cyclic oligomers have advantageous properties of resulting in a sustained, controlled ketone blood level over a period of hours (column 3, lines 53-55). Therefore, one having ordinary skill in the art would have been motivated at the time of the instant invention to modify Martin et al.'s practice by administering a cyclic oligomer of 3-hydroxyacid such as a cyclic oligomer of the instant formula (I) to result in the practice of the instant invention with a reasonable expectation of success.

With respect to the recitation of "producing a physiologically acceptable ketosis in a human or animal" in the preamble of claim 8, the effect of "producing ketosis in the animal" is an activity is expectedly present in the prior art method and thus does not limit the claim. This is because the active step of oral administration in the instant method is the same as that of the prior art method, and the administered subject is an animal as in both the instant method and the prior art method, when the same cyclic oligomer of 3-hydroxyacids is administered, the effect of "producing ketosis in the animal" is expected, in absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,323,237. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented invention makes obvious the instant claimed invention.

In particular, the patented invention teaches a method of administering a cyclic oligomer of a formula that is identical to the formula (I) of the instant invention. Although, the patented invention does not recite the effect of "producing a physiologically acceptable ketosis in a human or animal" in the instant invention, this effect is a feature that is inherently present in the patented method because the patient population of the patented invention embraces the population of "a human or animal" of the instant invention.

Claims 8-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/763,393. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application makes obvious the instant invention.

In particular, the copending Application teaches a method of administering a cyclic oligomer of a formula that is identical to the formula (I) of the instant invention. Although, the copending Application does not recite the effect of "producing a physiologically acceptable ketosis in a human or animal" in the instant invention, this effect is a feature that is inherently present in the copending Application because the

patient population of the copending Application embraces the population of "a human or animal" of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy L. Zhang whose telephone number is (571)-272-8270. The examiner can normally be reached on Mon.- Fri. 8:30am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nancy Zhang
Patent Examiner
AU1614
(571)-272-8270

BRIAN-YONG S. KWON
PRIMARY EXAMINER

Brian Kwon
Primary Examiner
AU1614
(571)-272-0581